

Improving the Hepatitis B Birth Dose Rate at UNC Hospitals

By

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Abstract

Introduction:

Re-emergence of vaccine-preventable diseases has become a public health problem in the United States. Vaccine refusals are now a common occurrence for many reasons and leave populations susceptible to infectious disease. The purpose of this study is to examine the immunization rate of one specific childhood vaccine, the Hepatitis B birth dose given prior to discharge from the hospital, at UNC Hospitals in Chapel Hill, North Carolina, and the patient and provider perceptions surrounding it, in order to suggest future quality improvement measures at a hospital level for improving immunization rates.

Methods:

The first part of this study consisted of a retrospective chart review of all births at UNC Hospital for the first quarter of 2014. I collected data on Hepatitis B vaccination, mother's Hepatitis B status, provider team, and other demographics in order to estimate the birth dose immunization rate as well as examine specific characteristics of vaccine refusers. The second part of this study was a small face-to-face interview project in which I spoke to patients and providers about their views and practices on the Hepatitis B birth dose using a survey I developed to administer in the newborn nursery at UNC Hospitals. I synthesized data from both the chart review and interviews to suggest policy changes.

Results:

I reviewed chart data from 722 births in the first quarter of 2014 and revealed a Hepatitis B birth dose refusal rate of 18.0% at UNC Hospitals. Infants who did not receive the birth dose before discharge were more likely to have a white, slightly older mother and private insurance than were those who did receive the vaccine inpatient. In the chart data, patients served by private family medicine providers and Chapel Hill Children's Clinic had the highest refusal rates of receiving the vaccine while the infants were still inpatient. The interviewed patients cited health and prevention as the most important reason for Hepatitis B vaccination, followed in frequency of mention by recommendations from their health care provider. Waiting to get the vaccine in the outpatient setting was the most frequent reason for inpatient refusal. Individual providers have varying methods to approach the birth dose with patients, resulting in the inconsistent refusal rates across specialties.

Conclusion:

UNC Hospitals can improve the birth dose immunization rate by making quality improvement changes that place importance on provider recommendation, making sure that providers offer patients clear explanations of the risks of forgoing inpatient immunization, and focusing efforts specifically on those providers who have high refusal rates. Other hospital-wide policy changes, such as making the birth dose an opt-out instead of opt-in through the electronic medical record ordering system, are likely to improve immunization rates.

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Table of Contents

Abstract.....	i
Acknowledgements.....	ii
Table of Contents.....	iii
List of Tables and Figures.....	iv
Introduction.....	1
Background and Significance.....	2
Methods.....	4
Findings: Chart Review, Parent Interviews and Provider Perspectives Converge on Areas for Improvement.....	7
Conclusion.....	15
References.....	17
Tables.....	19
Figures.....	23
Appendix A, Limited Systematic Review.....	30
Appendix B, Methods.....	39

List of Tables and Figures

Table 1.....	19
Table 2.....	20
Table 3.....	21
Table 4.....	22
Figure 1.....	23
Figure 2.....	24
Figure 3.....	25
Figure 4.....	26
Figure 5.....	27
Figure 6.....	28
Figure 7.....	29

Introduction

Last year, 189 cases of measles were reported in the United States, over three times the average 60 cases typically seen each year and the second largest number since the year 2000, when measles was considered “eliminated” from the country (1). In 2010, the state of California reported 9120 cases of pertussis, or whooping cough, the most in one year since 1947. Study of the outbreak region revealed clustering of nonmedical exemptions, or refusals for some reason other than a medical condition, to be one of many contributing factors (2). In California and other states, refusal rates have been rising over the past few years (3). These data show a disturbing trend that will ultimately lead to more outbreaks of easily-prevented communicable diseases in the United States.

One reason for an increase in refusals is that since vaccination has become widespread, infectious disease rates have plummeted. Most people now have never encountered measles or polio and have forgotten the severity of vaccine-preventable diseases (4). The media and pop-culture views of vaccines have become more prominent than is the evidence-based medical information provided to patients at the physician’s office. Fear of the vaccine has now outstripped fear of the disease. These themes apply to many vaccines, especially those given to young children. Mothers strive to do what is best for their children, and, unfortunately, misinformation and fear can lead to refusal of vaccinations that are shown to protect the child from disease. This is a public health problem that we see unfold right from the very beginning, when an infant leaves the hospital without the first dose of Hepatitis B vaccine.

Background and Significance

Hepatitis B is blood-borne and sexually transmitted virus that can be transmitted to an infant vertically, from the mother during birth, or horizontally, through household or environment exposure. Although transmission rates are highest in adults, HBV is a serious matter during infancy because about 90% of children who contract HBV in their first year of life will go on to develop chronic infection (5). Patients who have chronic HBV infection may go on to develop later complications of liver failure or cancer.

With the goal of decreasing the burden of disease and lowering transmission rates of HBV, the Advisory Committee on Immunization Practices (ACIP) presented new guidelines in 2005. To prevent perinatal and early childhood disease, the guidelines include this recommendation: “administer a birth dose of hepatitis B vaccine to medically stable infants who weigh $\geq 2,000$ g and who are born to HBsAg-negative mothers” before hospital discharge (6). This recommendation is supported across specialties and endorsed by the American Academy of Pediatrics, the American Academy of Family Physicians, and the American College of Obstetricians and Gynecologists. Despite the time elapsed since the updated recommendation, the Hepatitis B birth dose rate in the United States was estimated to be only 64.1% in 2010 (7). As a country, we have a long way to go to achieve the Healthy People 2020 goal of 85% birth dose immunization (8).

Many variables explain the low Hepatitis birth dose rate, and hospital policy is one of them. Some hospitals simply do not have a policy to offer HBV immunization to all newborns prior to discharge (9). Many providers believe their patient population to be low risk (10) and consequently place little importance on the birth dose when they plan on providing a dose at the two month visit. However, risk factors for HBV infections cannot be identified in more than 30% of people infected (11), indicating the importance of universal immunization. In addition, studies

have shown that those patients who receive the Hepatitis birth dose are more likely to complete the HBV series on time, by age 19-35 months (12) as well as to stay up-to-date on other childhood vaccines (13). To acknowledge the hospitals and birthing centers that succeed in achieving a high birth dose rate ($\geq 90\%$), the Immunization Action Coalition (IAC) awards the distinction of “Hepatitis B Birth Dose Honor Roll” (14).

Some vaccine studies examine demographic patterns and reasons for vaccine refusal in order to focus efforts on that specific population. Maternal characteristics of high educational level and high income were shown to be associated with refusal of the HBV birth dose (9). Data from the National Immunization Survey showed that children below the poverty level were actually more likely to receive the birth dose than were children above the poverty level (7). These demographics reflect those found in studies that examined parent demographics of other childhood vaccinations as well (15). When asked for the reason for childhood vaccination refusals, parents acknowledged concern over safety of the vaccine as the primary factor (15-17). Regardless of vaccine acceptance or refusal, most parents found vaccine information from their physician to be credible and valuable, and hesitant parents often chose to vaccinate after having an open discussion with their child’s physician (16). These themes and demographic patterns associated with vaccine refusal are potential avenues at which to target future interventions to increase vaccination coverage.

My quality improvement study was designed to examine the perinatal Hepatitis B vaccination rate at UNC Hospitals in two ways – first, through a retrospective chart review that allows me to also identify demographic patterns of refusal, and second, through interviews with patients and providers that provide insight into ideas and perceptions about the birth dose. The information I collected and present here is meant to serve as a stepping stone toward improving the overall rate at UNC Hospitals through future quality improvement measures.

Methods

Data Collection

This study comprises two parts – Part A, a retrospective chart review of births at UNC Hospitals and Part B, interviews of patients' caretakers (almost entirely their parents) as well as providers at UNC Hospitals. From here forward these parts will be addressed separately.

Part A: Retrospective Chart Review

The primary purposes of this part of the study were to estimate the Hepatitis B vaccination rate of infants prior to hospital discharge at UNC Hospitals and observe patterns in the demographics of those who refused the vaccine. I reviewed charts of all births in the first quarter of the year, which included births from December 30, 2013 to March 29, 2014. From the charts, I extracted data on Hepatitis B vaccination, mother's Hepatitis B status, hospital care team, particularly the dominant specialty of the team (e.g. Family Practice, Pediatrics, or others), and other demographic information (see Chart Extraction Tool in Appendix B). I recorded data without identifiers in order to preserve patient anonymity.

Part B: Interviews

I conducted in-person interviews to assess patient and provider perceptions of perinatal Hepatitis B vaccination. I conducted them between April 28, 2014 and May 30, 2014, meaning that none of the parent/caregivers I interviewed were a part of the chart review study. Patient interviews took place in the patient rooms located in Newborn Nursery at UNC Hospitals. I selected respondents by identifying English-speakers on the patient whiteboard, excluding the patients from Piedmont Health Services, a federally qualified health center that serves a large Hispanic population. Upon entering a room, I excluded the patient if I found she did not speak English because communication of interview questions would likely be unclear. I

also excluded a couple of interviews during which the parent/caregiver did not appear to understand what I was asking or responded to a question in an unclear manner. Interview questions addressed importance of vaccine, reasons for refusal, and provider team (see Parent/Guardian Interview Protocol in Appendix B).

I had originally intended to conduct provider interviews in conjunction with patient parent interviews. However, the nature of hospital-based care made it too difficult to obtain accurate accounts of each patient-provider interaction. Most of my provider interviews, thus, were brief exchanges with interns and attending physicians in the newborn nursery. In order to gain a more comprehensive knowledge of viewpoints, I contacted some physicians via phone or e-mail to learn their thoughts and ideas about perinatal Hepatitis B vaccination. This allowed me to interview representatives from both family medicine and pediatrics.

I submitted both the chart review and interview portions of the study to the UNC Institutional Review Board, who ruled this project “not human subjects research” because of its quality improvement goal (UNC IRB No. 13-4077).

Analysis Plan

Part A: Retrospective Chart Review

I reviewed the charts for a total of 727 births that took place in the first quarter of 2014. Five infants were stillbirths or passed away shortly after birth and were excluded from analysis, leaving a total of 722 live infants the charts of whom I could analyze. I operationalized ethnicity, vaccination status, provider group, and insurance type variables by assigning numeric codes in order to perform statistical analysis. I sorted and grouped the data according to vaccination acceptance/refusal. I used Microsoft Excel to perform simple statistics on each group and the entire birth cohort overall. I also used the Zip Codes of refusals to create a Geographic Information System (GIS) map to show distribution of refusers across geographical regions.

Part B: Interviews

I conducted a total of 106 patient interviews over the given dates. Interview data were organized in Microsoft Excel according to date of interview. I operationalized the variables vaccination status, reason for refusal, importance of vaccine, and provider team in simple ordinal or binary codes to allow for easy analysis, and I then performed simple statistical calculations in Excel. I was informed that after an educational discussion with one family, the family then chose to vaccinate their child in the hospital. Because I was analyzing under an Intention to Treat strategy, I kept this family in the “refusal” category.

I recorded other information from open-ended questions in the provider interviews in a separate document with the intention to use these data as an illustrative complement to the statistical analysis.

Findings: Chart Review, Parent Interviews and Provider Perspectives

Converge on Areas for Improvement

Part A: Retrospective Chart Review

My review of all births at UNC Hospital in the first quarter of 2014 revealed an overall vaccination refusal rate of 18.0% (See Table 1) among the 722 infants who survived at least to time of vaccination for whom I had chart data. The birth cohort was ethnically diverse, with 42.8% white and 19.3% African American infants; the remaining infants were coded in the chart by health care providers in the categories of “Asian”, “other”, and “unknown”. The average age of the mother was 29.5 years, with a range from 15 years to 45 years. Insurance type was split almost evenly between public and private, with slightly more patients having public insurance (52.8%). The vast majority of infants were cared for by the UNC Pediatrics provider team (78.4%), followed by Family Medicine (14.3%), Piedmont Health Services, and the private providers, including private family medicine practices (referred to as External FM in chart data) and Chapel Hill Children’s Clinic (CHCC).

Upon examination of vaccine acceptances and refusals, I observed the shifts in demographics between these two groups that the literature suggests. The refusal group was made up of patients with older, predominantly white mothers who were more likely to have private insurance (see Table 2). This pattern has been observed in previous vaccination refusal studies (15). The source of the pattern is not particularly clear, but women with higher socioeconomic status and education level may have access to and use resources outside of physician visits (e.g. social media, internet, etc.), to learn about vaccines. These searches inevitably lead to personal accounts of health problems that are attributed to vaccines and faulty information from anti-vaccine groups. Concerned mothers who come across these sites may not believe everything they read, but the stories might be enough for them to doubt vaccine safety.

If we accept private insurance as a rough proxy for socioeconomic status, it follows that the mothers of higher socioeconomic status may be overrepresented among refusers, although the relationship between insurance status and wealth is not perfect. White mothers are also a much larger proportion of the refusal group than that of the overall cohort, and each of the other ethnicities are concomitantly a smaller proportion of the refusal group than of the overall cohort, although each change in proportion varies in magnitude.

The chart review also shows differences by provider team. Most infants are cared for by the UNC Health Care Pediatrics service after delivery. However, several other groups care for infants as well, including the UNC Health Care Family Medicine service, Piedmont Health Services (PHS), the federally qualified health center, Chapel Hill Children's Clinic (CHCC), a private practice, and a number of external (non-UNC Health Care) private family medicine physicians. Vaccination refusals are not evenly distributed within or across these different provider teams, and this variation indicates that the role of the provider and how he or she approaches the Hepatitis B vaccination influences the vaccination rate. For example, virtually all CHCC and external FM patients appear to be vaccination refusals (see Figure 1). The results of the provider interviews (discussed at greater length below) suggests that parents receiving care from these private providers are told they can receive their first dose of Hepatitis B vaccination at their first outpatient visit, and they are told that this is standard protocol. My research cannot ascertain whether the primary reason for this practice is private providers who are not quite up to date on CDC recommendations, a preference for directing vaccination payment to their own practice, some combination of these, or some other reason entirely.

It is also difficult to blame refusals on specific services, as their numerous individual providers may have different practice preferences. Just one or two high-volume providers with high refusal rates may skew a whole service's distribution of vaccinations. This could very well be happening with the UNC Health Care Family Medicine service, the only provider team apart

from the private groups whose representation was greater in the refusal group than in the original cohort, but the data don't permit this kind of analysis at the level of the individual provider.

Number of refusals may also be a reflection of the patient population served by the provider. PHS patients are part of an underserved population, including a large number of Hispanics and other immigrants. Typically, as seen in practice and studies (18), these patients refuse vaccination infrequently. One reason for this observation may be that, culturally, the doctor-patient relationship is more paternalistic in these populations. Americans value autonomy and often do not hesitate to challenge a recommendation, but many other cultures may view this practice as disrespectful and, consequently, accept physicians' plans without pushback.

In order to assess the geographical distribution of refusals, I used Google Maps to create a GIS map. Originally I was hoping to find "hotspots" of high refusal numbers in geographical areas known to be of higher education and socioeconomic status. However, I found a more concentric pattern of refusal numbers surrounding the location of UNC Hospital. This is to be expected, as the population of patients seen at UNC Hospital is most dense in the geographically near regions and sparser as you travel farther away. But it is also true that the geographic area around UNC Hospitals is one of considerable affluence and educational attainment, precisely those characteristics associated with refusal.

Part B: Interviews of Parents and Providers

Parents and Caregivers

I used my survey to interview caregivers, most of whom were parents, of the infants. Much of the interview data is a compilation of what multiple caregivers/parents of a single infant provided. These interviews produced a 19.8% refusal rate, similar to the 18.0% I found in my chart review of a different set of births. One reason for the slightly higher rate among interview

respondents could be that I excluded non-English speakers and all PHS patients, patients who typically accept Hepatitis B vaccination as observed in practice, from the interview sample. I also included “Pending” vaccinations as “vaccine acceptances” in my interview sample because these parents were merely waiting on nurses to administer the vaccine that had already been ordered by the physician.

I asked why the Hepatitis B vaccination was important or not important for their child, and parents responded with a variety of answers (see Table 3). The most common pro-vaccination answer by far was for the health of their child and/or prevention of Hepatitis B (59.4%). The second most common answer was that the vaccine was recommended and/or that it was part of normal protocol for child care (18.9%). Many of these parents had previous children who had received the vaccine and planned to vaccinate their newborn in the same way. Some parents understood the Hepatitis B vaccine to be normal procedure for newborn care or something to check off before hospital discharge. Surprisingly, a large number of parents cited only the doctor’s recommendation, without any reference to prevention or health, as the reason the vaccine was important. This finding suggests that physician discussion and recommendation is influential, and making use of physician influence could be a potential focus area for further improvement. Provider recommendation and communication is cited as an important factor of vaccine acceptance in former studies as well (16, 17). Other less common reasons for importance cited by parents include protection of society and “other”, which included the overall importance of all vaccines.

I asked all respondents why the Hepatitis B vaccine was or was not important for their child. A substantial minority of all respondents did not know why the vaccine is important (8.5%). This finding was unexpected, and shows another area with room for improvement. It is unclear whether these patients responded in this manner because they might have felt as if they were being quizzed and did not want to say a “wrong answer”, or if they were truly unaware of the

importance of vaccines because providers had not offered adequate discussion, or because parents had low health literacy, or for other reasons. Parents who believed the vaccine was *not* important said that it was unnecessary and/or the child had a low risk for disease (7.5%) and that the vaccine was not safe or contained harmful ingredients (2.8%). Some parents elaborated on their belief that their child was low-risk by saying that the child was not sexually active, using IV drugs, or going to daycare in the near future.

Most “refusers” could perhaps better be characterized as “postponers.” In order to maintain open lines of communication and obtain frank responses, I very carefully assured several hesitant parents that I was interested in their perceptions and was not there to judge their actions or change their mind. I simply wanted to have an open conversation, and after hearing what they had to say, I answered questions and referred them to the cdc.gov resources. Of the refusers, most parents did plan to get the Hepatitis B vaccination for their child, but preferred to wait until an outpatient visit with their pediatrician (47.6%). This decision to wait was greatly influenced by the practice preferences of their provider (discussed below). The next most common reason for refusal was that their child was too young or small or had already undergone many “pokes” in the hospital (28.6%). Others believed the vaccine was unnecessary or said the child did not have a risky lifestyle (19.0%). Others were concerned about dangerous vaccine ingredients (14.3%), or they had spiritual/religious/personal reasons not to vaccinate (9.5%). Almost 5% (4.8%) gave other reasons. Some of the parents who declined Hepatitis B vaccination because of their child’s lack of risky lifestyle affirmed that they intended to get the other standard childhood vaccines. This reaction may be comparable to what we see now with parents who refuse the HPV vaccination for adolescents.

After examination of all parent interview data, I was able to determine estimates of provider team care of patients. UNC Pediatrics accounted for 72.6% of patients, UNC Family Medicine cared for 20.8%, and CHCC took care of 4.7% (see Table 3, Figure 5). These

numbers, although they did not include PHS or the non-UNC private Family Medicine practitioners, resembled the chart review numbers of 78.4%, 14.3%, and 1.5% respectively. Family Medicine and CHCC appeared in larger proportions in this smaller interview sample size. This shift in representation of provider groups likely contributed to the slightly higher refusal rate (discussed above), as both Family Medicine and CHCC contributed higher refusal rates. Upon stratification by provider team, CHCC showed the highest refusal rate with essentially 100% of the CHCC parents eschewing the Hepatitis B vaccine prior to discharge (see Figure 6). In talking to these patients, I was able to clarify that the CHCC providers recommend that their patients wait until an outpatient pediatrician visit to receive the vaccine. As I noted above, I cannot ascertain the reasons for this practice preference, but they could include that providers do not know the updated CDC recommendation (or do not think it is important), the practice would like to maintain their patients' vaccination records all in one place, or perhaps the practice would like to benefit financially from delaying this vaccine and being able to charge for it during an office visit.

UNC Family Medicine ranked next in refusals at 31.8%, but the large UNC family medicine service varies in its preferences from provider to provider. Although I did not analyze the data according to individual provider, I noticed distinct patterns during the chart review that reflected a strong correlation between individual provider and whether the patient received the vaccine inpatient. Here again we see that individual practice and procedure strongly affects whether patients defer vaccination to the outpatient setting. Overall, UNC Pediatrics had the lowest refusal rate at 11.7%. In speaking to numerous providers, I found that many, if not most, providers (including nurse practitioners, residents, and attendings) presented the vaccine as a standard procedure before discharge and were less likely to present parents with later vaccination as an option (discussed below). This group had very few parents choosing to defer

vaccination to the outpatient setting. Most of their refusals were for the other reasons discussed above.

Although the data become somewhat confusing when stratified and examined, we should keep in mind that the largest group of “refusers”, 47.6%, did intend to accept the vaccine in the outpatient setting.

Although the UNC Pediatrics team had the lowest refusal rate, they still contributed the largest proportion of overall number of refusals simply because they were the providers of care to the largest proportion of newborns (see Figure 7). This finding reminds us that even if we focus future quality improvement efforts on the teams with higher refusal rates, the whole system may benefit from a hospital-wide change that affects all teams.

What surprised me most about refusal data was that patients born in the same hospital received different standards of care. Who took care of the patient greatly influenced whether that infant received the CDC-recommended perinatal dose prior to discharge. The typical anti-vaccine concerns over artificial ingredients or dangers to health were not absent from these data, but they made up a much smaller proportion of the refusers than I had expected. This finding that providers may matter more than does anything else is especially important because most patients do not know the CDC recommendation or the implications of NOT receiving the vaccine inpatient, and leaving their child at risk, while the payment for eventual vaccination is going to a different provider.

Providers

Talking to providers enabled me to gather information on current perinatal Hepatitis B vaccination practices. I began by trying to complete the Provider Protocol interview (found in Appendix B) but quickly realized the difficulty of keeping up with individual patient interactions from the provider perspective. I also found that I did not get much substantive information, so I

quickly changed my methods to instead talk to a variety of providers in person, over the phone, or through e-mail. I asked them how they approach perinatal Hepatitis B vaccination with their patients and what can be done to improve the vaccination rate. Summary excerpts of the results are found in Table 4.

Although I did not have a large number of provider perspectives, the ones I did obtain somewhat reflected the data discussed above. The pediatricians in general approached vaccination more as a normal part of standard infant care protocol to be done prior to discharge, while the family doctors presented vaccination in the outpatient setting as a noninferior option. However, some pediatricians made the point that outpatient vaccination was not a big problem if the patient was responsible and had good follow-up care. Representatives from both pediatrics and family medicine came up with vaccination rate improvement ideas, including having a discussion about concerns and vaccine importance with parents, and making the vaccination an opt-out instead of an opt-in or creating a quality metric in the electronic medical record on a systems level.

Conclusions

My study leads me to three main areas of improvement for UNC Hospital Hepatitis B birth dose rate: Emphasizing the importance of provider recommendation; Offering an explanation to parents of risks to the child who does not receive the vaccine; and targeting providers with low birth dose rates for further education about current recommendations. Both the results of my study and the literature point to the importance of provider recommendation of the vaccine as a large factor in parents' decision-making. Physicians may not fully understand the effect they may have by simply recommending the vaccine to patients personally. This is an easy, non-time-consuming change that could make a difference. Explaining the child's risks of contracting Hepatitis B if left unvaccinated is more time-consuming but equally as important. At UNC Hospitals, a number of interviewed patients did not know why the birth dose was important, even after being given the CDC vaccine information sheet. Parents' lack of understanding could emerge from many different causes, as I discussed above, but this observation demonstrates an opportunity for providers to step in and make sure patients know the risks of not vaccinating. This explanation is also very important for parents who believe their child is not at risk during infancy.

Finally, targeting specific providers and services that have lower in-hospital acceptance rates, including certain family medicine providers and private providers, would likely improve the overall vaccination rate. Because most of the "refusals" seen by these providers appear to be "postponers" instead – those who are deferring vaccination to an outpatient visit, it would be useful to learn the providers' reasons for this suggestion and proceed from there. It is possible that some providers simply may not realize the CDC recommendation change. In addition, using other quality improvement methods, such as tracking and displaying birth dose rates by various hospital services, and displaying criteria to reach the IAC's Birth Dose Honor Roll, may also provide incentive for providers to pay more attention to this goal.

On a hospital level, changing the Hepatitis birth dose to an opt-out instead of an opt-in through EMR orders may also help improve rates, as it has done in previous studies (19). As it stands now, providers must add the birth dose as an order instead of having it as part of the standard set of newborn orders that are automatically added. Although having the order as part of the standard order set may not specifically facilitate patient-doctor communication about the vaccine, it would likely increase coverage rates.

The goal of increasing the perinatal Hepatitis B vaccination rate is challenging but attainable. With the cooperation and dedication of the providers at UNC Hospitals' newborn nursery, we may soon join the ranks of other hospitals on the Birth Dose Honor Roll in protecting our patients from Hepatitis B.

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Tables

Table 1: Population Characteristics of Births at UNC Hospital in the First Quarter of 2014

Characteristic		Percentage (n = 722)
Hep B Vaccination	Accept	82.0
	Refuse	18.0
Ethnicity of Infant	White	42.8
	African American	19.3
	Asian	4.2
	Other	30.1
	Unknown	3.9
Age of Mother (avg)		29.5 yrs
Provider Team	UNC Pediatrics	78.4
	Family Medicine	14.3
	PHS	4.3
	CHCC	1.5
	External FM	1.5
Insurance	Public	52.8
	Private	47.2

SOURCE: chart abstractions (by S. Klodnicki) of all births surviving to vaccination at UNC Hospitals, 1Q 2014.
 5 deceased infants excluded from table. PHS = Piedmont Health Services; CHCC = Chapel Hill Children's
 Clinic, private pediatric office (not part of UNC); External FM = external family medicine (not part of UNC)

Table 2: Population Characteristics of Vaccine Refusals and Acceptances at UNC Hospitals in the First Quarter of 2014

		Refusals (n = 131)	Acceptances (n = 591)
Ethnicity of Infant	White	72.5%	36.4%
	African American	13.0%	20.5%
	Asian	1.5%	4.7%
	Other	9.9%	34.5%
	Unknown	3.1%	3.9%
Age of Mother (avg)		31.2 yrs	29.1 yrs
Provider Team	UNC Pediatrics	46.6%	85.4%
	Family Medicine	33.6%	10.0%
	PHS	3.1%	4.6%
	CHCC	8.4%	0.0%
	External FM	8.4%	0.0%
Insurance	Public	29.0%	58.0%
	Private	71.0%	42.0%

SOURCE: chart abstractions (by S. Klodnicki) of all births surviving to vaccination at UNC Hospitals, 1Q 2014.

5 deceased infants excluded from table. PHS = Piedmont Health Services; CHCC = Chapel Hill Children's Clinic, private pediatric office (not part of UNC); External FM = external family medicine (not part of UNC)

Table 3: Vaccine Receipt, Importance, and Provider Team: Interviews of Parents at UNC Hospitals Newborn Nursery

Category	Percent (number)
Received Vaccine	
No	19.8 (21)
Pending*	17.9 (19)
Yes	62.3 (66)
Importance of Vaccine**	
Why Vaccine is Important	
Health/prevention	59.4 (63)
Recommended/normal protocol	18.9 (20)
Protect society	2.8 (3)
Other	6.6 (7)
Unable to answer ("not sure")	8.5 (9)
Why Vaccine is NOT Important	
Unnecessary/low risk of disease	7.5 (8)
Vaccine not safe	2.8 (3)
Other	0.9 (1)
No answer	1.9 (2)
Provider Team	
UNC Pediatrics	72.6 (77)
Family Medicine	20.8 (22)
CHCC	4.7 (5)
No answer	1.9 (2)

SOURCE: Parent/Caregiver interviews and provider interviews, all conducted by author, from April to May 2014 at UNC Hospitals Newborn Nursery.

Parent/caregiver interviews n = 106

*Patients were waiting on vaccine to be given (had already been ordered by physician)

**Patients could choose more than one category

***most common "other" reason was general importance of vaccines

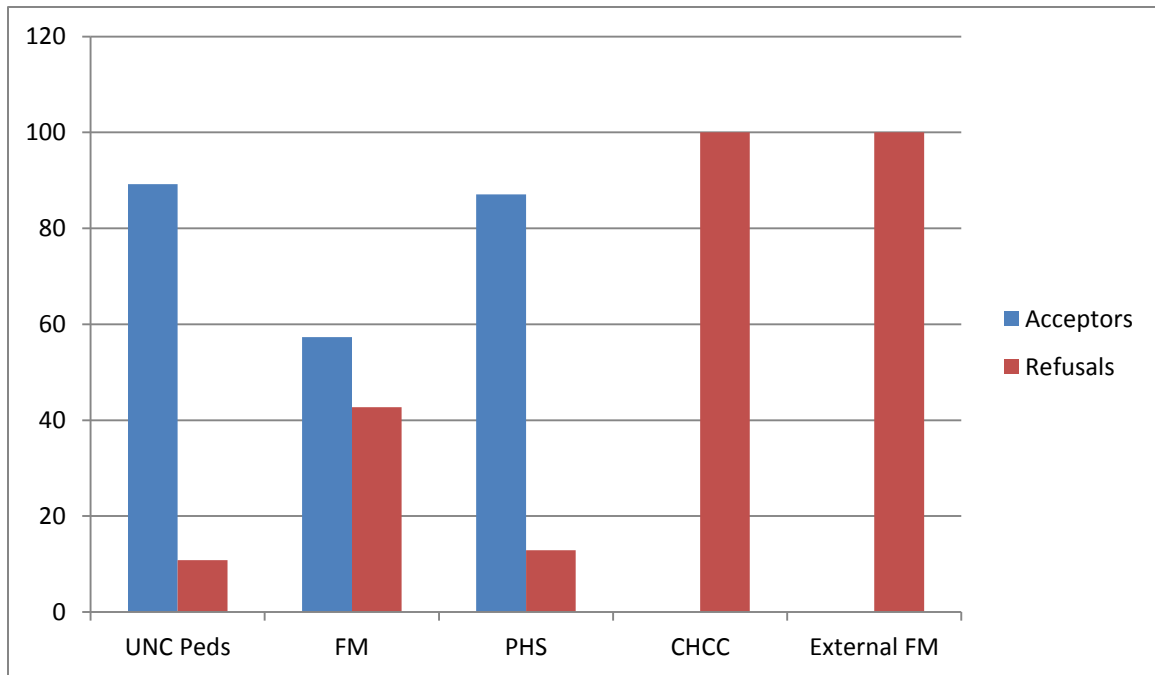
Table 4: Provider Interview Data

Open-ended responses about current practices (How do you approach perinatal Hep B vaccination?)
<p>Some physicians ask (about the vaccine) and if the patient says no, they move on.</p> <p style="text-align: right;"><i>– Med/peds Intern</i></p>
<p>Tell the patient “Here we give the Hep B vaccine...” and normalize instead of giving the choice.</p> <p style="text-align: right;"><i>- Pediatrics Intern</i></p>
<p>Can give the vaccine in hospital or outpatient, especially if parent has concerns. Make routine.</p> <p style="text-align: right;"><i>– 3rd yr Family Medicine Resident</i></p>
<p>Usually broach the subject at the first meeting (mother’s admission) and lump together with other normal things.</p> <p style="text-align: right;"><i>- Pediatrics Attending</i></p>
<p>(I) somewhat discourage the patient from getting the vaccine inpatient and do not see the purpose in giving the vaccine early to reliable patients. I offer/recommend to wait to the 2 month check-up unless parents have chronic Hep B or high-risk behavior. Patients elect to get the vaccine inpatient about 50% of the time. I’m open to changing my practice if there is overwhelming evidence but right now I don’t see a pressing need to do so.</p> <p style="text-align: right;"><i>- Family Medicine Attending</i></p>
Open-ended responses about ideas for improvement
<p>If patient refuses vaccine, the provider should find out why and explain the importance. If patient is deferring vaccine and planning to follow up with outpatient pediatrician, it’s not a big problem.</p> <p style="text-align: right;"><i>– Med/peds Intern</i></p>
<p>Make vaccination opt-out instead of opt-in (in EMR ordering system).</p> <p style="text-align: right;"><i>– 3rd yr Family Medicine Resident</i></p>
<p>Make Hep B vaccination a quality metric in EPIC.</p> <p style="text-align: right;"><i>- Pediatrics Attending</i></p>

SOURCE: Parent/Caregiver interviews and provider interviews, all conducted by author, from April to May 2014 at UNC Hospitals Newborn Nursery.

Figures

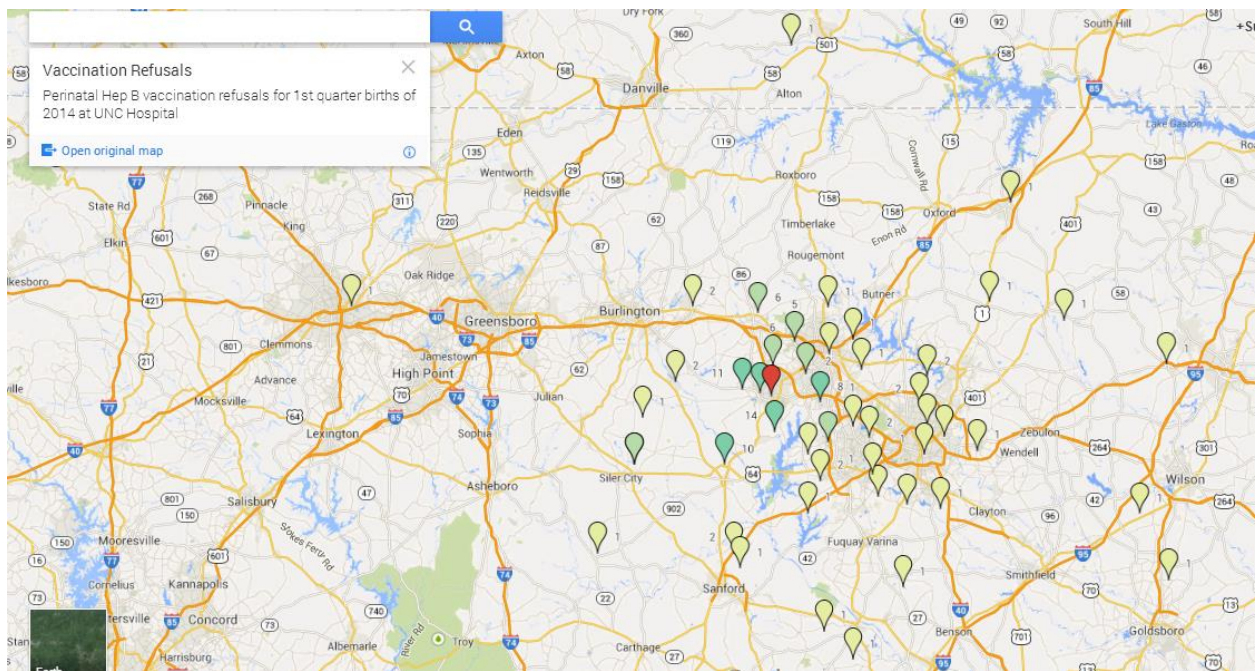
Figure 1: Refusals By Provider Team for the 1st Quarter, 2014



SOURCE: chart abstractions (by S. Klodnicki) of all births surviving to vaccination at UNC Hospitals, 1Q 2014

FM = Family Medicine; PHS = Piedmont Health Services; CHCC = Chapel Hill Children's Clinic, private pediatric office (not part of UNC); External FM = external family medicine (not part of UNC)

Figure 2: GIS Map of Hepatitis B Birth Dose Refusals at UNC Hospital, 1st Quarter 2014



SOURCE: chart abstractions (by S. Klodnicki) of all births surviving to vaccination at UNC Hospitals, 1Q 2014

Each marker represents 1 zip code



1-2 Refusals



3-7 Refusals

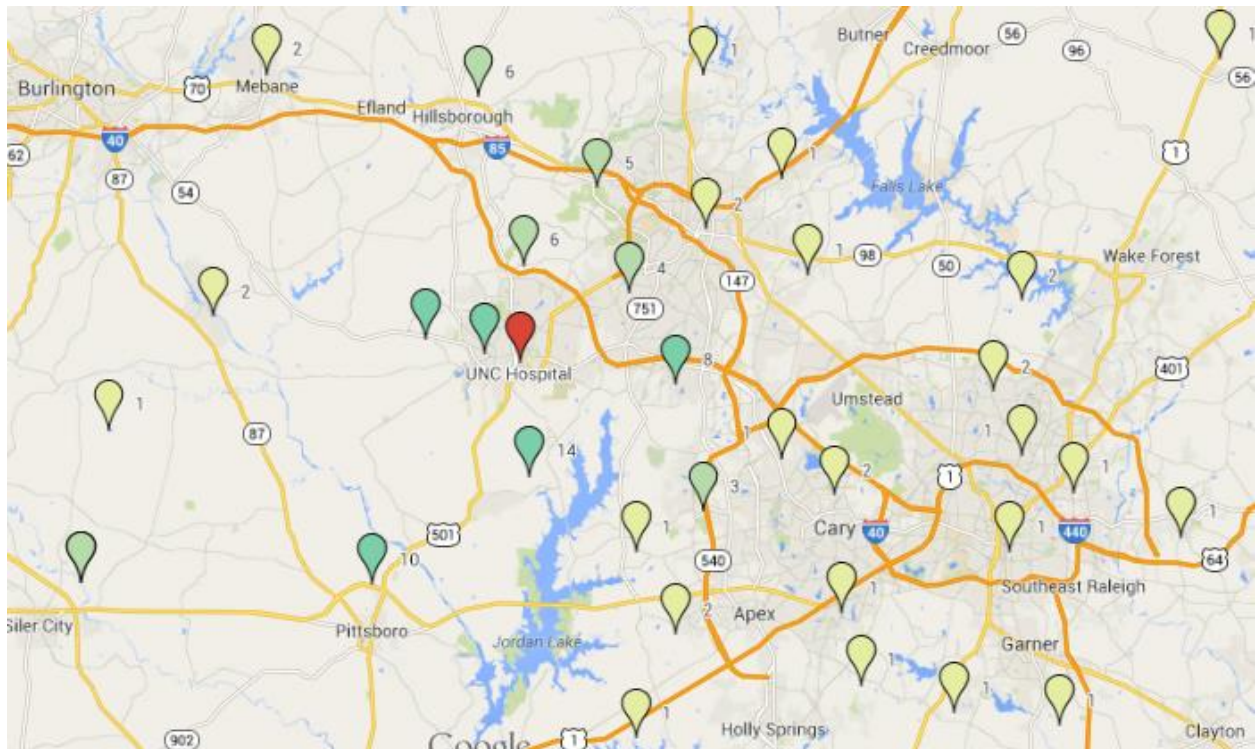


8+ Refusals



UNC Hospitals

Figure 3: GIS Map of Hepatitis B Birth Dose Refusals at UNC Hospital, 1st Quarter 2014,
Focused on UNC Hospital



SOURCE: chart abstractions (by S. Klodnicki) of all births surviving to vaccination at UNC Hospitals, 1Q 2014

Each marker represents 1 zip code



1-2 Refusals



3-7 Refusals

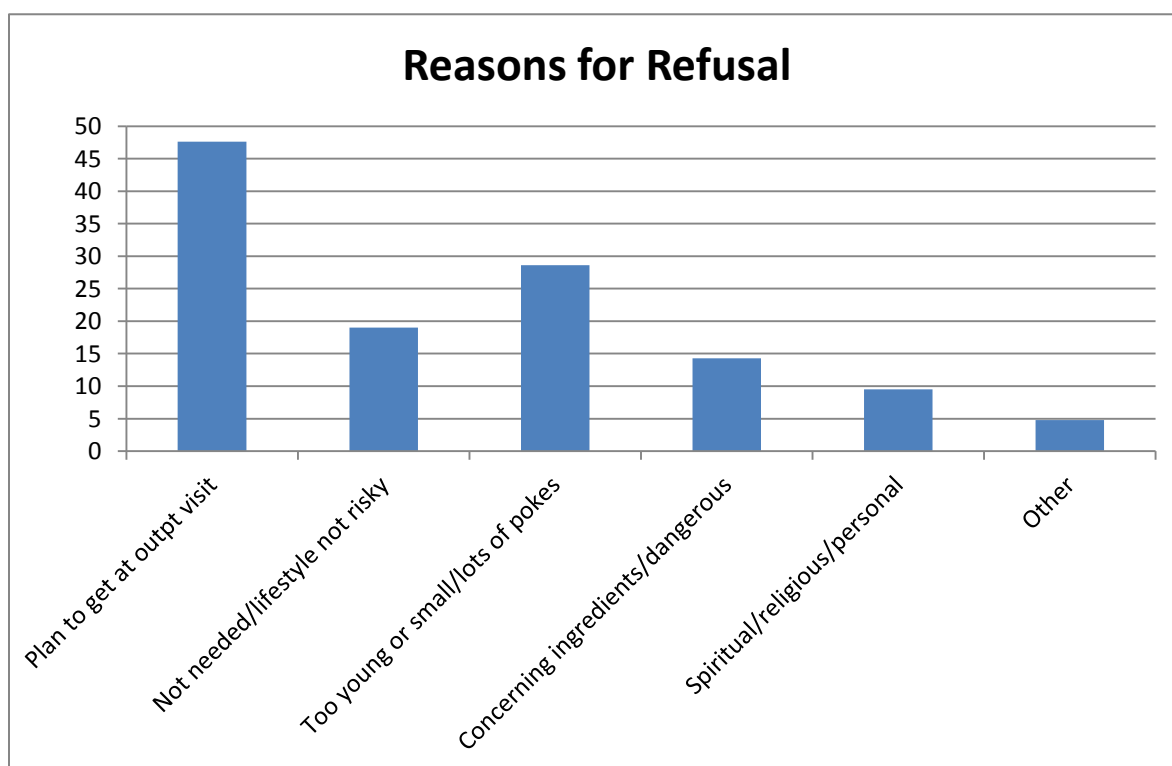


8+ Refusals



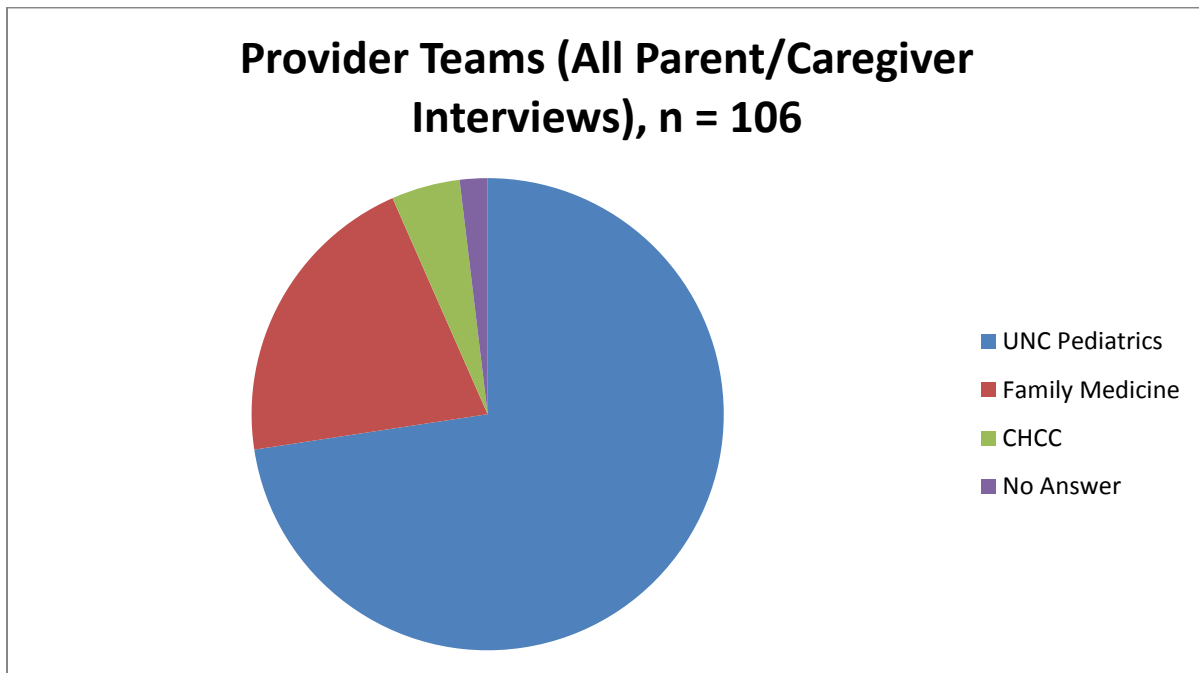
UNC Hospitals

Figure 4: Patient Interview Reasons for Hepatitis B Birth Dose Refusal By Percentage



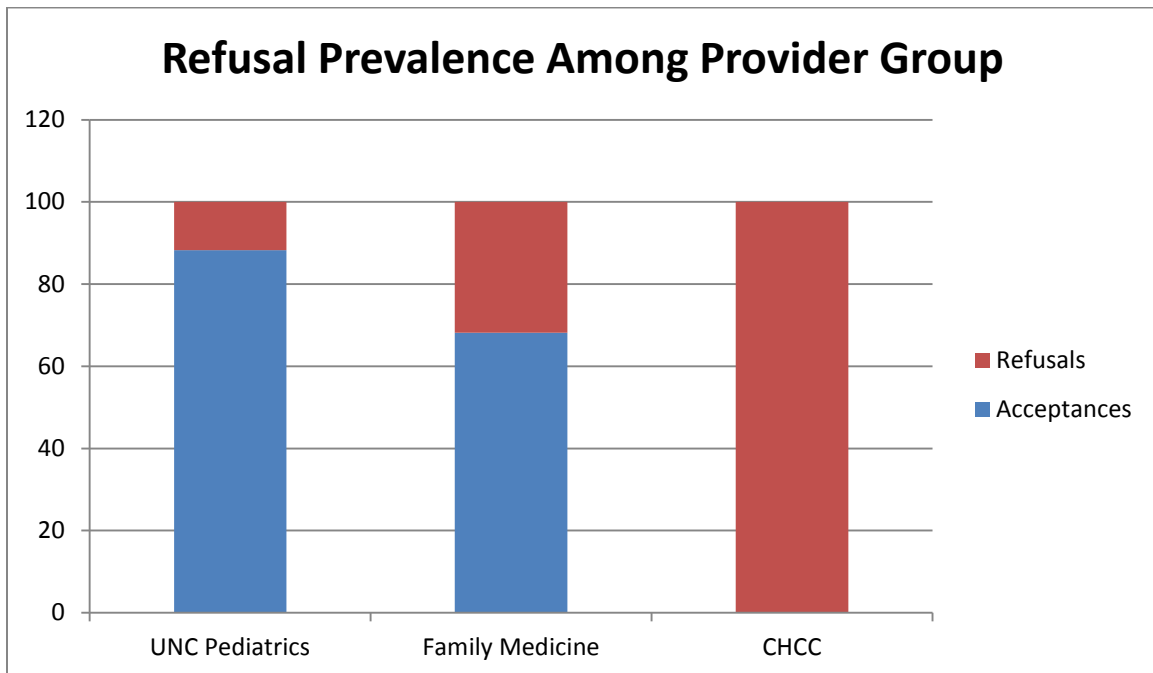
SOURCE: Parent/Caregiver interviews and provider interviews, all conducted by author, from April to May 2014 at UNC Hospitals Newborn Nursery.

Figure 5: Provider Teams of All Parents/Caregivers Interviewed



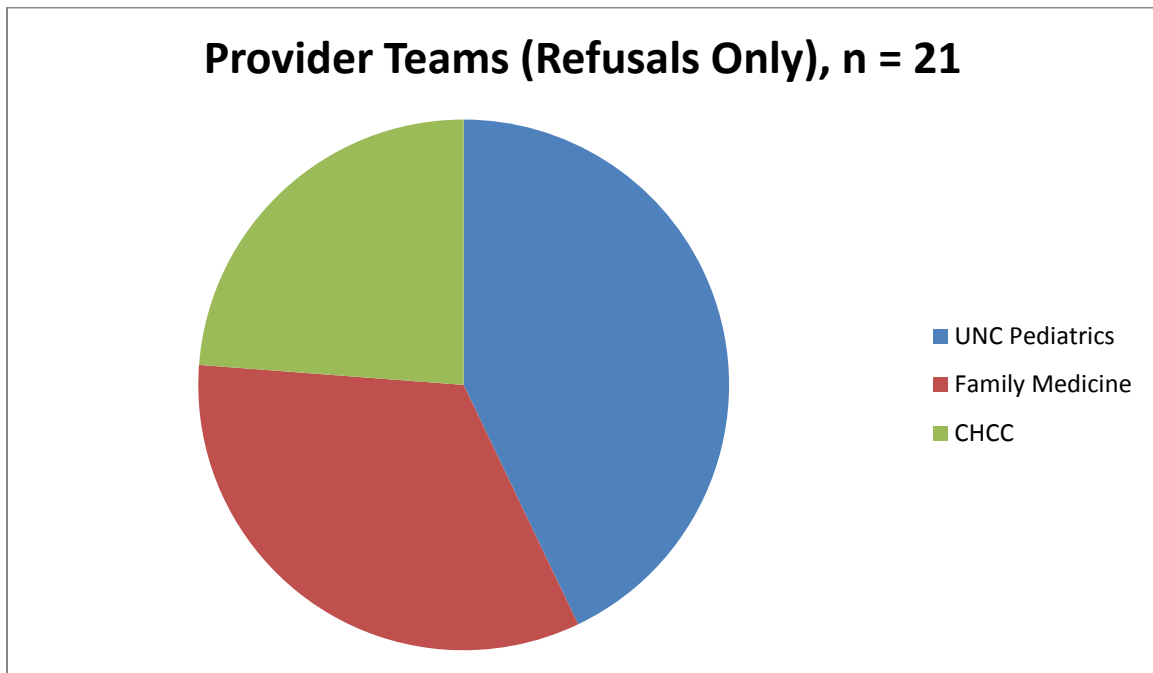
SOURCE: Parent/Caregiver interviews and provider interviews, all conducted by author, from April to May 2014 at UNC Hospitals Newborn Nursery.

Figure 6: Refusals and Acceptances of the Hepatitis B Birth Dose by Provider Team



SOURCE: Parent/Caregiver interviews and provider interviews, all conducted by author, from April to May 2014 at UNC Hospitals Newborn Nursery.

Figure 7: Provider Teams of Parent/Caregiver Interview Refusals



SOURCE: Parent/Caregiver interviews and provider interviews, all conducted by author, from April to May 2014 at UNC Hospitals Newborn Nursery.

Appendix A, Limited Systematic Review

Introduction

Childhood vaccination is arguably one of the greatest developments in public health over the last century (Diekema, 2005). The United States has seen dramatic drops in infectious disease rates since the widespread adoption of childhood vaccination schedules. In 2010, an estimated 70.2% of children aged 19-35 months received the recommended combined vaccination series (CDC, 2011). However, barriers to vaccination, including lack of access and accurate medical information on vaccines, continue to interfere with improvement of childhood immunization rates. As a country, we have a ways to go before achieving our Healthy People 2020 goal to “increase immunization rates and reduce preventable infectious diseases” (Dept of HHS, 2010).

Methods to improve childhood vaccination rate have been tried on various levels by various societies. However, the literature evaluating existing methods that are effective in increasing childhood vaccination rate is limited.

The purpose of this limited systematic review is to evaluate existing literature on childhood vaccination policy and practices in developed countries in order to find potential methods that may be applied to jurisdictions in the United States to increase childhood vaccination on a national level.

Methods

To identify relevant articles, I searched PubMed for *childhood vaccination policy* and applied the filters for humans and English. I scanned the resulting 237 titles and abstracts to include only articles from the developed nations of Canada, Europe, the United States, and the United Kingdom. I excluded articles that were older than 20 years (published before 1994) because I wanted to focus on more recent policies and their effects. After review I decided to

include only articles that addressed vaccination in young children less than 12 years old to maintain a focus on the bulk of vaccines given early in life. I also decided to exclude studies in which the intervention was only aimed at reducing a socioeconomic disparity. Although focusing interventions on specific groups of undervaccinated people may increase overall vaccination coverage, such as low SES groups, this review excludes these interventions to focus on broader policies that effect the larger population. Six articles were included in this systematic review.

Results

The childhood vaccination rate after an instituted policy or program was compared to the prior rate in 4 of the 6 articles. One article surveyed public clinics to determine factors that contributed to high vaccination rates in the state of Georgia. The other article evaluated the effects of CDC funding for childhood vaccinations. The main outcomes examined were vaccination coverage rates. In 4 of the 6 articles, a variation of the 4:3:1:3:3 schedule (4+ doses DTaP, 3+ doses polio, 1+ dose MMR, 3+ doses Hib, and 3+ doses Hep B) in an age range somewhere within 12 months to 35 months old was the primary outcome measure. In one study influenza vaccination rate of children less than 12 years old was the primary outcome measure. In the other study, MMR coverage of children less than 2 years old was measured. The evaluated interventions varied in structure and intensity, ranging from making vaccines free of charge to using a phone/mail/home visit vaccination reminder system. Methods of evaluation also varied greatly and included mailed and phone surveys, home interviews, and use of national immunization databases. The articles are described below and described in the Summary Table.

Dietz et al evaluated high vaccination coverage rates in Georgia public clinics through a 1994 mail survey sent to lead nurses or immunization coordinators in all 227 state public clinics.

They obtained a 100% response rate from clinics which were stratified by coverage rate. 4:3:1 series coverage data of 21-23 month old children was extracted from clinic records by an independent staff from the Georgia Immunization Program. Univariate analysis revealed that high coverage rates were associated with small clinic size, a high proportion of patients enrolled in WIC, nonurban settings, and numerous vaccine practices/policies. Multivariable analysis showed that 8 of greater than 150 factors remained associated with high coverage rates: no wait time, telephone reminder system, home visits for defaulters, restricting WIC vouchers when children are undervaccinated, and motivational factors for nurses such as incentives to raise coverage and participation in assessments by state immunization staff.

Ciofi et al evaluated childhood vaccination rates 21 regions and autonomous provinces as well as three urban areas with population greater than 1 million in the country of Italy. They used a national EPI-survey in 2003 and conducted home interviews with parents using a standardized questionnaire. The purpose of the survey was follow up a similar survey done in 1998 in order to gauge whether changes since 1998 had made a difference in coverage. Their sample included 4602 children, 731 (16%) of which were selected from alternates to replace those that could not be contacted or declined participation. Children in the sample were between 12 and 24 months old with a mean of 18.5 months. Outcome measures included immunization coverage of 12-24 month olds (3+ doses each of diphtheria-tetanus, pertussis, Hep B, Hib, and 1 dose MMR), where vaccines were given, whether they were given free of charge, and reasons for missed or delayed vaccinations. Overall, more than 95% children received immunization coverage, and every region surpassed the 90% mark except for one. Non-mandated vaccination coverage, such as Hib at 87% and MMR at 77%, remained lower. 95% of vaccines were given at public Local Health Units, and 88% families received all vaccines free of charge.

Moran et al evaluated the Universal Influenza Immunization Program in Ontario that started for all residents over the age of 6 months in the year 2000. They used a telephone

survey in September 2007 to contact families of 4854 children after exclusion for unknown vaccination status and obtained a 70.2% response rate from those eligible. Of those surveyed, the parent most responsible for caring for the child (PMR) was commonly a female in a married/common law union with the average age of 37. The average surveyed family was a family of four with two children aged 6 months to 11 years. The primary outcome measures were influenza vaccination coverage rate for children less than 12 during the 2006-2007 flu season and comparison to rates of other Canadian provinces that used targeted vaccination programs. Information on location of where the vaccine was given, reasons for receiving or refusing the vaccines, presence of chronic medical conditions, and other demographics were collected. Ontario achieved 22.0% complete coverage for healthy children 2 – 11 years old, 30.8% complete coverage for children 2 – 11 years old with chronic medical conditions, and 10.2% complete coverage for all children 6 – 23 months old. Complete coverage required two doses of vaccine for those less than 9 years old, and one dose for those older than 9. The combined coverage rate (both complete and partial immunization statuses) for children 6 – 23 months old was 24.9%, similar to that of Manitoba but lower than those of Nova Scotia, Quebec, Saskatchewan, and Alberta. The most common reason for receiving the vaccine was a health reason, followed by vaccine recommendation (this was more prevalent in the 6 – 23 month range). The most common reason for refusal was that it was not needed, followed by concerns and barriers to access.

Espey et al evaluated the effects of the Clinical Prevention Initiative (CPI) in the state of New Mexico. CPI adopted childhood vaccination as a topic in 2002 and established the “Done By One” program, which consolidated the Advisory Committee on Immunization Practices (ACIP) recommendations into a shorter time frame to accomplish full immunization by age 1. The outcome measures included 4:3:1:3:3 coverage rates in 19 – 35 month old children, obtained from the National Immunization Survey (NIS), and change in state immunization rank in the United States. The NIS showed a 13.8% increase in cumulative vaccination coverage

from 2002 to 2005, up to 83.5%. New Mexico also moved up state rank from 49th in 2002 to 36th in 2005.

Cushon et al assessed the effectiveness of the Immunization Reminders Project in the Saskatoon Health Region (SHR) from October 2007 to October 2009. The project included up to 5 phone calls, a letter, and a home visit to caregivers of children 14 – 20 months old who were behind on their immunization schedule. The sample included 24,540 children. The primary outcome measure was MMR coverage rates for children residing in SHR at the time they turned 2 years old that were recorded in the Saskatchewan Immunization Management System (SIMS). These rates were also stratified by geographical region, which oftentimes reflected socioeconomic status. Overall, MMR coverage increased in 2 year olds from 2007 to 2009 (68.6% to 75.7%), as well as in each geographical area. Coverage rate was significantly lower in low-income “core” neighborhoods, sometimes by over 20%.

Rein et al used a fixed-effects model to evaluate CDC immunization grant funding in 56 U.S. jurisdictions (50 states and 6 cities) from 1995 to 2003. Population characteristics included 73.2% vaccination coverage, 14.7% below the federal poverty line (FPL), 24.5% at 5 times the FPL or higher, 5.8% unemployment, 7.6% without health insurance. The primary outcome measure was 4:3:1:3:3 coverage in children 19 – 35 months old, obtained using the NIS. The effect of financial assistance funding per capita was positive and statistically significant. A \$10 increase in funding per capita corresponded to a 1.6% increase in vaccination coverage. Increases in unemployment were also associated with statistically significant increases in coverage.

Discussion

Overall, this limited systematic review elucidated a few successful methods to increase childhood vaccination. However, before adopting such methods on a state or national level, the limitations and external applicability must be evaluated.

The Georgia public clinic study obtained an excellent response rate with little risk of selection bias as they surveyed all Georgia public clinics. However measurement bias could easily have skewed results if clinic records were not accurate. Recall bias and the Hawthorne effect could also play roles through use of a survey. These biases would likely overestimate vaccination rate, although inaccurate records would likely underestimate it. Several other studies made use of surveys, including Ciofi et al and Moran et al. Even the studies that used reputable vaccination records, such as the SIMS or NIS, could introduce potential bias. The NIS is a list-assisted random-digit-dialing telephone survey followed by a mailed survey to the child's immunization provider (CDC, 2014). Exclusion of patients without landlines, those who declined, and inaccuracy of records or failure to respond on the provider's part may all add to a bias of uncertain direction and magnitude. Other potential sources of bias in these studies include large numbers of people who declined participation (seen in Ciofi et al and Moran et al), possibly leading to overestimation of vaccination rates if those who declined were refusals or noncompliers.

Precision was an issue with a few studies. Some confidence intervals in the CDC funding study were fairly wide, including that for vaccination coverage (Rein et al, 2006). The SHR study had relatively tight confidence intervals except for the core neighborhood stratum, which was attributed to a small sample size (Cushon et al, 2012). The CPI study also had wide confidence intervals in the NIS data (Espey et al, 2007). The wider the confidence interval, the less precise we can be about the results reported.

Some of the studies had other limitations that may limit the strength of their conclusions. For example, the Georgia public clinic study did not track staffing or WIC changes over time, two factors that could have contributed to the success of their increased vaccination rates (Dietz et al, 2000). The SHR study examined effects of the Immunization Reminders Project, but it is difficult to say that the increased immunization rates were solely a result of that project and that no other factors played a role (Cushon et al, 2012). The CDC funding study looked at

allocations, not expenditures, and analyzed only seven years of data. They were also unable to make any conclusions on how their CDC funding affected other sources of vaccination funding (Rein et al, 2006). The CPI study was done in New Mexico, a state with large Hispanic and Native American population, largely uninsured with a high rate of childhood poverty (Espey et al, 2007). Perhaps a similar initiative would not be as successful in a wealthier less diverse population. Each of these studies was performed in different locations with varying populations and health care systems, implying that application in a different setting may or may not be as successful.

Despite these limitations and potential biases, many of the methods found to be successful in this review could potentially be applied to similar populations. The one method that did not show an improvement was the Universal Influenza Immunization Program in Ontario compared to targeted programs of other Canadian provinces (Moran et al, 2009). Each of the other studies showed moderate improvements with the given methods, and the Georgia study found some clinic characteristics associated with increased vaccination rate (Ciofi et al, Espey et al, Cushon et al, Rein et al, and Dietz et al).

I can conclude, upon individual study analysis, most of these methods worked at least moderately, perhaps with other factors working as well, for the given populations. Thus, it may be effective to try some of the practices on a local or state level in the U.S. with the hope that successful methods will eventually become widespread.

Summary Table

Article	Study Population	Primary Outcome Measure	Intervention Evaluated	Location	Main Result	Potential for Bias & Limitations
Dietz et al (2000)	21 – 23 month old children	4:3:1 (4+ DTap, 3+ polio, 1+ measles) coverage	Georgia public health clinics	Georgia	8 factors associated w/ high coverage rates	Medium
Ciofi et al (2004)	12 – 24 month old children	3:3:1:3:3 coverage	National goal of 95% coverage, new national immunization schedule, free vaccines within National Health Service	Italy	>95% received 3 doses polio, DT, pertussis, HBV. Hib coverage at 87%, MMR/measles coverage ≥ 16 mos. at 77%.	Medium - High
Moran et al (2009)	< 12 y.o. children	Influenza vaccine coverage	Universal Influenza Immunization Program	Ontario	Rates not better than those in targeted programs	Medium - High
Espey et al (2007)	19 – 35 month old children	4:3:1:3:3 coverage	Clinical Prevention Initiative “Done By One” program	New Mexico	↑ 13.8% vaccine coverage from 2002 to 2005 (up to 83.5%)	Low - Medium
Cushon et al (2012)	2 year-olds	MMR coverage	Immunization Reminders Project	Saskatoon Health Region, Saskatchewan	MMR coverage increase from 68.6% to 75.7% from 2007 to 2009	Low
Rein et al (2006)	19 – 35 month old children	4:3:1:3:3 coverage	CDC Immunization Grants Program Funding	United States (50 states + 6 cities)	\$10 increase in funding per capita corresponded to a 1.6% increase in vaccination coverage	Low - Medium

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Appendix B, Methods

Chart Extraction Tool

[illegible]

Hepatitis B Vaccination Improvement

PARENT/GUARDIAN Interview Protocol

Hello, my name is Susie Klodnicki. I am a medical student and public health student working on a project to help more babies get the Hepatitis B vaccination here at UNC. I am working with Dr. Carl Seashore and Dr. Sue Tolleson-Rinehart. Do you mind if I ask a few questions about the vaccine today?

[If yes]: My project has been reviewed by the UNC Institutional Review Board...

[if No]: Thank you! I'll be around for a while – please let me know if you change your mind!

1. Has your baby gotten the Hepatitis B vaccine?

Yes

No

[IF NO] 1.A. Why hasn't your baby had the vaccination?

2. Why do you think the Hepatitis B vaccine IS/IS NOT important for your baby's health?

3. Who talked to you about the Hepatitis B vaccine today? [get provider role; if parent/guardian doesn't spontaneously provide, say "And was that the...doctor, resident, nurse, medical student, someone else?]

[note if parent CANNOT SAY which provider talked to him/her]

4. After you talked about the vaccine, did you have any questions left that you still didn't have answers to?

5. Thank you! One last question: who cared for you and the baby at the time of the birth? People in obstetrics, or Family Medicine, or something else?

Is there anything else you'd like to mention about the vaccine? Thank you again for your time!

Hepatitis B Vaccination Improvement

PROVIDER PROTOCOL

Hello, my name is Susie Klodnicki. I am a medical student and public health student working on a project to improve Hepatitis B perinatal vaccination here at UNC. I am working with Dr. Carl Seashore and Dr. Sue Tolleson-Rinehart. I am talking to parents about their experience with the Hep B vaccine, and also matching their perceptions to those of providers. This project has been reviewed by the IRB. I am maintaining a patient code only long enough to link parent and provider responses, and am not including any identifying information on these forms.

1. Did the patient receive the Hepatitis B vaccine? (circle) yes no

2. If parent/guardian refused, what reason did the parent give?

3. Did parents/guardians bring any questions or concerns about the vaccine to your attention? What were they?

4. [IF NO VACCINATION ONLY]: What is the one thing you, as the provider, could have done to improve the likelihood of vaccination for this child?

5. [ALL]: What are the THREE things you think the hospital can do to improve vaccination rates over all?

6. Which hospital team are you on?

Thank you! Is there anything you'd like to add about improving Hepatitis B vaccination rates?